



## ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPPT-2021-0693; FRL-9157-01-OCSPP]

### **EPA Administrator Determination Extends TRI Reporting Requirements to Certain Contract Sterilization Facilities; Notice of Availability**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Notice.

**SUMMARY:** The Environmental Protection Agency (EPA) is announcing the extension of the Toxics Release Inventory (TRI) reporting requirements to certain contract sterilization facilities under its discretionary authority through the Emergency Planning and Community Right-to-Know Act (EPCRA). Pursuant to this authority, EPA decided to extend the reporting requirements for ethylene oxide releases and other waste management activities to 29 contract sterilization facilities; and to extend the reporting requirements for ethylene glycol to 16 of those facilities. EPA is applying this discretionary authority in response to concerns over potential health effects of ethylene oxide exposure and in support of the public's right-to-know.

**FOR FURTHER INFORMATION CONTACT:** Stephanie Griffin, Data Gathering and Analysis Division, Office of Pollution Prevention and Toxics, (7410M), Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460-0001; telephone number: (202) 564-1463; email address: [griffin.stephanie@epa.gov](mailto:griffin.stephanie@epa.gov).

### **SUPPLEMENTARY INFORMATION:**

#### **I. Executive Summary**

##### *A. Does this action apply to me?*

The determination, signed by the Administrator on December 16, 2021 (Ref. 1), is directed to the 29 specific facilities identified in Unit II.A. of this document. This determination may also be of interest to the general public and users of TRI data, including researchers, non-profit organizations in the environmental and public health sectors, and state and local

governments. Since other entities may also be interested, the Agency has not attempted to describe all the specific entities that may be affected by this action.

*B. What is the Agency's authority for taking this action?*

EPA made this determination pursuant to EPCRA section 313(b)(2), [42 U.S.C. 11023], which provides EPA with the authority to extend the reporting requirements of EPCRA section 313 to any particular facility at the Administrator's discretion:

The Administrator, on [their] own motion . . . , may apply the requirements of [EPCRA section 313] to the owners and operators of any particular facility that manufactures, processes, or otherwise uses a toxic chemical listed under [EPCRA section 313(c)] if the Administrator determines that such action is warranted on the basis of toxicity of the toxic chemical, proximity to other facilities that release the toxic chemical or to population centers, the history of releases of such chemical at such facility, or such other factors as the Administrator deems appropriate.

*C. How can I get copies of this document and other related information?*

The docket for this determination, identified by docket identification (ID) number EPA-HQ-OPPT-2021-0693, is available at <http://www.regulations.gov>. Due to the public health concerns related to COVID-19, the EPA Docket Center (EPA/DC) and Reading Room is closed to visitors with limited exceptions. The staff continues to provide remote customer service via email, phone, and webform. For the latest status information on EPA/DC services and docket access, visit <https://www.epa.gov/dockets>.

*D. What action is the Agency taking?*

Pursuant to EPCRA section 313(b)(2), the EPA Administrator signed a determination on December 16, 2021 that extended TRI reporting requirements to 29 facilities for ethylene oxide and, in 16 cases, for ethylene glycol (Ref. 1). After considering facility-specific factors including chemical toxicity, proximity to population centers, the facility's history of chemical releases, and other factors the EPA Administrator deems appropriate (such as potential environmental justice concerns), the EPA believes the public would benefit from increased information disclosure related to the releases of ethylene oxide (and in some cases, ethylene glycol) at these facilities. This discretionary authority extends TRI reporting requirements to facilities identified by the

Administrator if they manufacture, process, or otherwise use the TRI toxic chemical over the respective activity threshold over the course of a year, regardless of the facility's industry sector (i.e., North American Industry Classification System (NAICS) code) or number of full-time employee-equivalents. Going forward, EPCRA section 313(a) will require these facilities to report to TRI if they meet TRI reporting thresholds for on-site activities involving ethylene oxide or ethylene glycol over the course of a year.

*E. Why is the Agency taking this action?*

Ethylene oxide is a flammable, colorless gas used to sterilize equipment, such as medical equipment, among other manufacturing applications, including the manufacture of ethylene glycol. In December 2016, EPA's Integrated Risk Information System (IRIS) Program updated its cancer assessment for ethylene oxide and characterized the chemical as "carcinogenic to humans" by the inhalation route of exposure (Ref. 2).

Congress established the TRI to further the public's right to know about chemical releases from certain facilities in their communities. However, not all facilities are currently subject to TRI reporting requirements (see 40 CFR part 372). EPA recognizes and shares the public's concerns about the harmful effects of ethylene oxide on human health and the environment, so the Agency exercised its authority under EPCRA section 313(b)(2) to increase the information available to the public on releases of ethylene oxide and ethylene glycol from certain sterilization facilities that were not currently subject to TRI reporting requirements.

*F. What are the estimated incremental impacts of this action?*

This determination extends TRI reporting requirements to 29 facilities for ethylene oxide, and to 16 of those facilities for ethylene glycol. While this action does not directly require facilities to report to TRI or use EPA's TRI reporting forms, these facilities may ultimately submit up to 45 TRI reporting forms pursuant to EPCRA section 313(a) and 40 CFR part 372, if chemical activity reporting thresholds are met for those chemicals over the course of a year. 45 TRI reporting forms would result in estimated incremental impacts of up to \$107,408 annually

across all affected entities. There are no annualized operation or maintenance costs. All affected entities have annual cost impacts of less than 1%.

## **II. Background**

### *A. Which facilities does this determination apply to?*

The Administrator's determination extends the TRI reporting requirements in EPCRA section 313 to the following facilities, for the indicated chemicals. The Agency has created a separate docket for each facility, which includes any correspondence between EPA and the facility on this matter:

1. Andersen Sterilizers, 3154 Caroline Drive, Haw River, NC 27258; Ethylene oxide (CASRN: 75-21-8); Docket ID: EPA-HQ-OPPT-2021-0694.

2. Boston Scientific Corporation, 8 Industrial Drive, Coventry, RI 02816; Ethylene oxide (CASRN: 75-21-8), Ethylene glycol (107-21-1); Docket ID: EPA-HQ-OPPT-2021-0696.

3. ETO Sterilization-Plant #2, 2500 Brunswick Avenue, Linden, NJ 07036; Ethylene oxide (CASRN: 75-21-8), Ethylene glycol (107-21-1); Docket ID: EPA-HQ-OPPT-2021-0697.

4. Fuchs North America, 3800 Hampstead Mexico Road, Hampstead, MD 21074; Ethylene oxide (CASRN: 75-21-8); Docket ID: EPA-HQ-OPPT-2021-0698.

5. International Sterilization Laboratory, 217 Sampey Road, Groveland, FL 34736; Ethylene oxide (CASRN: 75-21-8); Docket ID: EPA-HQ-OPPT-2021-0699.

6. Isomedix Operations, Inc., 1435 Isomedix Place, El Paso, TX 79936; Ethylene oxide (CASRN: 75-21-8); Docket ID: EPA-HQ-OPPT-2021-0700.

7. Isomedix Operations, Inc., 1175 Isuzu Parkway, Grand Prairie, TX 75050; Ethylene oxide (CASRN: 75-21-8), Ethylene glycol (107-21-1); Docket ID: EPA-HQ-OPPT-2021-0701.

8. Isomedix Operations, Inc., 435 Whitney Street, Northborough, MA 01532; Ethylene oxide (CASRN: 75-21-8); Docket ID: EPA-HQ-OPPT-2021-0702.

9. LEMCO Ardmore, 3204 Hale Road, Ardmore, OK 73401; Ethylene oxide (CASRN: 75-21-8); Docket ID: EPA-HQ-OPPT-2021-0703.

10. Long Island Sterilization, 175 Wireless Boulevard, Hauppauge, NY 11788; Ethylene oxide (CASRN: 75-21-8); Docket ID: EPA-HQ-OPPT-2021-0704.
11. Medline Industries, 1160 South Northpoint Boulevard, Waukegan, IL 60085; Ethylene oxide (CASRN: 75-21-8), Ethylene glycol (107-21-1); Docket ID: EPA-HQ-OPPT-2021-0705.
12. Parter Medical Products Inc, 17115 Kingsview Avenue, Carson, CA 90746; Ethylene oxide (CASRN: 75-21-8); Docket ID: EPA-HQ-OPPT-2021-0707.
13. Professional Contract Sterilization, Inc., 40 Myles Standish Boulevard, Taunton, MA 02780; Ethylene oxide (CASRN: 75-21-8), Ethylene glycol (107-21-1); Docket ID: EPA-HQ-OPPT-2021-0708.
14. Sterigenics-Salt Lake City Facility, 5725 West Harold Gatty Drive, Salt Lake City, UT 84116; Ethylene oxide (CASRN: 75-21-8), Ethylene glycol (107-21-1); Docket ID: EPA-HQ-OPPT-2021-0714.
15. Sterigenics U.S. LLC, 2971 Olympic Industrial Court SE, Suite 116, Atlanta, GA 30339; Ethylene oxide (CASRN: 75-21-8), Ethylene glycol (107-21-1); Docket ID: EPA-HQ-OPPT-2021-0709.
16. Sterigenics U.S. LLC, 1302 Avenue T, Grand Prairie, TX 75050; Ethylene oxide (CASRN: 75-21-8), Ethylene glycol (107-21-1); Docket ID: EPA-HQ-OPPT-2021-0711.
17. Sterigenics US LLC, 84 Park Road, Queensbury, NY 12804; Ethylene oxide (CASRN: 75-21-8), Ethylene glycol (107-21-1); Docket ID: EPA-HQ-OPPT-2021-0713.
18. Sterigenics US, Inc., 4900 Gifford Avenue, Vernon, CA 90058; Ethylene oxide (CASRN: 75-21-8), Ethylene glycol (107-21-1); Docket ID: EPA-HQ-OPPT-2021-0716.
19. Sterigenics US, LLC, 18021 Withers Cove Park Drive, Charlotte, NC, 28278, Ethylene oxide (CASRN: 75-21-8), Ethylene glycol (107-21-1), EPA-HQ-OPPT-2021-0710.
20. Sterigenics US, LLC, 687 Wanamaker Avenue, Ontario, CA 91761; Ethylene oxide (CASRN: 75-21-8), Ethylene glycol (107-21-1); Docket ID: EPA-HQ-OPPT-2021-0712.

21. Sterigenics-Santa Teresa, NM, 2400 Airport Road, Santa Teresa, NM 88008; Ethylene oxide (CASRN: 75-21-8), Ethylene glycol (107-21-1); Docket ID: EPA-HQ-OPPT-2021-0715.

22. Sterilization Services of Tennessee, 2396 Florida Street, Memphis, TN 38109; Ethylene oxide (CASRN: 75-21-8), Ethylene glycol (107-21-1); Docket ID: EPA-HQ-OPPT-2021-0717.

23. Steris Inc., 380 90th Avenue Northwest, Coon Rapids, MN 55433; Ethylene oxide (CASRN: 75-21-8); Docket ID: EPA-HQ-OPPT-2021-0718.

24. Steris Isomedix Services Inc, 7685 Saint Andrews Avenue, San Diego, CA 92154; Ethylene oxide (CASRN: 75-21-8), Ethylene glycol (107-21-1); Docket ID: EPA-HQ-OPPT-2021-0720.

25. Steris Isomedix Services Inc, 3459 S Clinton Avenue, South Plainfield, NJ 07080; Ethylene oxide (CASRN: 75-21-8), Ethylene glycol (107-21-1); Docket ID: EPA-HQ-OPPT-2021-0721.

26. Steris, Inc., 43425 Business Park Drive, Temecula, CA 92590; Ethylene oxide (CASRN: 75-21-8); Docket ID: EPA-HQ-OPPT-2021-0719.

27. Steris-Isomedix Services, 2072 Southport Road, Spartanburg, SC 29306; Ethylene oxide (CASRN: 75-21-8); Docket ID: EPA-HQ-OPPT-2021-0722.

28. Steritec, Inc., 1705 Enterprise Street, Athens, TX 75751; Ethylene oxide (CASRN: 75-21-8); Docket ID: EPA-HQ-OPPT-2021-0723.

29. Trinity Sterile, Inc., 201 Kiley Drive, Salisbury, MD 21801; Ethylene oxide (CASRN: 75-21-8); Docket ID: EPA-HQ-OPPT-2021-0724.

*B. How did EPA select these facilities?*

In identifying these facilities, EPA considered a variety of data available on ethylene oxide usage and releases, including historical TRI data and data reported to other EPA programs. Information available to EPA suggests these contract sterilization facilities use the highest

amounts of ethylene oxide in this sector.

EPA believes that these facilities are likely to exceed the 10,000 pounds per year “otherwise used” TRI reporting threshold for ethylene oxide. While EPA’s discretionary authority to extend TRI reporting requirements to specific facilities is not limited to facilities that currently meet the TRI reporting thresholds, EPA determined that it is appropriate to consider the quantity of ethylene oxide or ethylene glycol potentially manufactured, processed, or otherwise used on-site when evaluating whether reporting requirements should be extended to certain facilities. In addition, EPA reviewed previous TRI reporting forms to identify which facilities may also be likely to exceed the chemical activity reporting thresholds for ethylene glycol.

EPA also considered other factors enumerated in EPCRA section 313(b)(2) in the identifying these facilities, including the facilities’ proximity to a population center (e.g., the density of the population, including children, living near the facilities) and other factors the Administrator deems are appropriate (e.g., proximity of the facilities to nearby schools and communities, especially those with potential environmental justice concerns).

*C. Did EPA conduct any outreach to facilities prior to this action?*

In October 2021, EPA sent letters to 31 facilities providing notice that EPA was considering exercising this discretionary authority. These letters also provided the facilities with the opportunity to respond or provide any additional information before EPA made its determination.

EPA received communications from 19 facilities. Some included inquiries on the scope of the discretionary authority under EPCRA section 313(b)(2) and TRI reporting; others acknowledged that the facility would be prepared to submit any TRI reporting forms to EPA should they be required by EPCRA section 313(a) and 40 CFR part 372. All communications with facilities under this authority have been uploaded to facility-specific dockets, which are listed in Unit II.A.

Additionally, one facility indicated that they no longer conduct any ethylene oxide

sterilization on-site, they have sold their previous sterilization establishment, and all sterilization activity has been contracted out-of-state. A separate facility also provided information to EPA regarding the size of and technology used in their operations to support their claim of using very low levels of ethylene oxide such that they would be unlikely to ever meet TRI reporting thresholds. After reviewing this information, EPA decided not to extend reporting requirements to these two facilities. Those facilities and their dockets are listed below:

1. Andersen Scientific, 1001 Aviation Parkway, Suite 600, Morrisville, NC 27560; Ethylene oxide (CASRN: 75-21-8); Docket ID: EPA-HQ-OPPT-2021-0695.

2. NovoSci Corporation, 2021 Airport Road, Conroe, TX 77301; Ethylene oxide (CASRN: 75-21-8); Docket ID: EPA-HQ-OPPT-2021-0706.

*D. What reporting may be required under EPCRA section 313(a) and 40 CFR part 372 following the Administrator's determination under EPCRA section 313(b)(2)?*

EPCRA requires reporting to provide information on releases and other waste management of TRI chemicals. This information is used by the public and assists EPA and other regulatory agencies in determining whether future regulations are needed. Among other data elements, facilities must report (1) the quantities of routine and accidental releases; (2) releases resulting from catastrophic or other one-time events of TRI chemicals; (3) the maximum amount (in ranges) of the TRI chemical on-site during the calendar year; and (4) the amount contained in wastes managed on-site or transferred off-site. Facilities reporting to TRI must submit either a Form R for each chemical, or a Form A Certification Statement for applicable chemicals. Form R is the standard TRI reporting form. Form A Certification Statement is a simplified certification form available to facilities to report on chemicals for which the facility neither (1) manufactures, processes, or otherwise uses above one million pounds; nor (2) exceeds 500 pounds for total quantities released or otherwise managed as waste on-site and quantities transferred off-site for waste management. More information on the data reported on TRI reporting forms, including instructions for reporting facilities, can be found in the current TRI Reporting Forms and



Instructions (Ref. 3).

Under EPCRA section 313(a) and 40 CFR part 372, the facilities listed in this notice may be required to submit TRI reporting forms for ethylene oxide (and ethylene glycol, where noted) if they manufacture, process, or otherwise use the chemical above the respective activity thresholds in 40 CFR 372.25. Reporting on ethylene oxide and ethylene glycol would begin with Reporting Year 2022, and Reporting Year 2022 forms from these facilities will be due to EPA by July 1, 2023. This reporting requirement will continue to apply for each subsequent reporting year where the facility's chemical activities meet or exceed the respective activity threshold.

### **III. References**

The following is a listing of the documents that are specifically referenced in this document. The docket includes these documents and other information considered by EPA, including documents that are referenced within the documents that are included in the docket, even if the referenced document is not physically located in the docket. For assistance in locating these other documents, please consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

1. U.S. EPA. Determination of the Administrator of the Environmental Protection Agency Under the Emergency Planning and Community Right-to-Know Act Section 313(b)(2) to Apply the Requirements of EPCRA Section 313 to Certain Contract Sterilization Facilities. December 16, 2021.

2. U.S. EPA. Evaluation of the Inhalation Carcinogenicity of Ethylene Oxide (EPA/635/R-16/350Fa). December 2016. Available at [https://cfpub.epa.gov/ncea/iris/iris\\_documents/documents/toxreviews/1025tr.pdf](https://cfpub.epa.gov/ncea/iris/iris_documents/documents/toxreviews/1025tr.pdf).

3. U.S. EPA. Toxic Chemical Release Inventory Reporting Forms and Instructions. Available at <https://www.epa.gov/tri/rfi>.

**Authority:** 42 U.S.C. 11023

Dated: December 21, 2021.

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